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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/577,426 | 04/27/2006 | Toshio Matsumoto | P29832 | 4734 |
| 7055 | 7590 | 12/13/2007 | EXAMINER | |
| GREENBLUM & BERNSTEIN, P.L.C. 1950 ROLAND CLARKE PLACE RESTON, VA 20191 | | | VO, HAI | |
| ART UNIT | PAPER NUMBER | | | |
| | 1794 | | | |
| NOTIFICATION DATE | DELIVERY MODE | | | |
| 12/13/2007 | ELECTRONIC | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gpatent@gpatent.com
pto@gpatent.com

| | | |
|------------------------------|--------------------------------------|---|
| Office Action Summary | Application No. 10/577,426 | Applicant(s) MATSUMOTO ET AL. |
| | Examiner Hai Vo | Art Unit 1794 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED. (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 18 October 2007.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1,2,4-12 and 14 is/are pending in the application.
- 4a) Of the above claim(s) 9-12 and 14 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1,2, and 4-8 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO/136/08)
 Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date _____
- 5) Notice of Informal Patent Application
 6) Other: _____

1. All of the art rejections are maintained.
2. The obviousness-type double patenting rejections are obviated by the terminal disclaimer.

Terminal Disclaimer

3. The terminal disclaimer filed on 10/19/2007 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of US Patent No. 7,272,219 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Election/Restrictions

4. Applicants are reminded of their right to request rejoinder of method claims with the product claims upon indication of the product claims as being allowable. The method claims must be commensurate with the allowed article claims, i.e. have been amended to recite all the features of the allowed article claims. See *In re Ochiai* 37 USPQ2d 1127.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 1, 2, and 4-6 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over JP 03-065579. JP'579 discloses a porous ceramic membrane comprising a calcium phosphate substrate having fine pores and a calcium phosphate coating on the substrate (pages 4 and 7). The coating contains 0.1 to 10% by weight of calcium phosphate that has a particle size of 100 nm or less and Ca/P ratio of 1.5 to 1.666. The calcium phosphate particles of the coating have the rod-like shape and dimensions within the range disclosed in the specification of the present invention (page 9). The coating has an average thickness of 2 μm , which is within the claimed range (page 10). The porous ceramic membrane has pores with an average pore diameter ranging from 200 to 500 nm (page 10). The porous membrane is useful as an absorbent (page 11). Likewise, it is clearly apparent that at least some of the pores of the coating are communicated with those of the substrate for successful absorption. Similarly, the surface coating would substantially inherently have plurality of three dimensionally interconnected nanopores so as to enable the porous membrane suitable as an absorbent. JP'578 teaches that the slurry is uniformly applied so as to form a uniform porous layer onto the substrate (page 8). Therefore, it is the examiner's position that the coating would be substantially formed on 100% of the wall

surfaces of the fine pores of the substrate. Accordingly, JP'579 anticipates or strongly suggests the claimed subject matter.

8. Claims 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 03-065579 as applied to claim 1 above, and further in view of JP 2003-073182. JP'579 is silent as to the substrate having a porosity of 40 to 98%. JP'182, however, teaches a porous calcium phosphate substrate as a bone substitute material having a porosity of 5 to 50% and a Ca/P ratio ranging from 1.5 to 1.7 (paragraphs 13 and 15). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to use the porous calcium phosphate substrate having a porosity as taught by JP'182 motivated by the desire to porous ceramic membrane with sufficient strength. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use the porous calcium phosphate substrate having a Ca/P ratio as taught by JP'182 motivated by the desire to produce the substrate having desired amount of hydroxyapatite having excellent biocompatibility for use as a bone substitute material.

Response to Arguments

9. The art rejections based on JP'579 have been maintained for the following reasons. Applicants contend that difference in processes will lead to two products which are not structurally the same. Applicants fail to provide any factual evidence or declaration in support of their assertion. The examiner notes that the porous membrane of JP'579 is not structurally different than the porous

ceramic body of the claimed invention. JP'579 discloses a porous ceramic membrane comprising a calcium phosphate substrate having fine pores and a calcium phosphate coating on the substrate (pages 4 and 7). The coating contains 0.1 to 10% by weight of calcium phosphate that has a particle size of 100 nm or less and Ca/P ratio of 1.5 to 1.666. The calcium phosphate particles of the coating have the rod-like shape and dimensions within the range disclosed in the specification of the present invention (page 9). The coating has an average thickness of 2 μm , which is within the claimed range (page 10). The porous ceramic membrane has pores with an average pore diameter ranging from 200 to 500 nm (page 10). The porous membrane is useful as an absorbent (page 11). Likewise, it is clearly apparent that at least some of the pores of the coating are communicated with those of the substrate for successful absorption. Similarly, the surface coating would substantially inherently have plurality of three dimensionally interconnected nanopores so as to enable the porous membrane suitable as an absorbent. JP'578 teaches that the slurry is uniformly applied so as to form a uniform porous layer onto the substrate (page 8). Therefore, it is the examiner's position that the coating would be substantially formed on 100% of the wall surfaces of the fine pores of the substrate. Accordingly, the art rejections are sustained.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hai Vo whose telephone number is (571) 272-1485. The examiner can normally be reached on Monday through Thursday, from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571) 272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

HV

/Hai Vo/
Primary Examiner, Art Unit 1794